EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Weining Wang on 11/05/09.

The application has been amended as follows:

In claim 92, line 2, after "from", replace "those" with ---said first---

In claim 95, line 2, after "from", replace "that" with ---said first---

Claims 126 and 127. (Canceled)

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance: The primary reason for allowance of the claims is the combination of superdisintegrant, tannic acid and hydrogel in the amounts recited in the claims. Applicant's declaration filed 3/16/2009 shows that in the absence of tannic acid, a composition comprising superdisintegrant and hydrogel does not expand and that the combination of tannic acid, superdisintegrant and hydrogel in the relative

amounts recited is necessary in order for the composition to achieve the expansion and strength suitable for the composition as a gastric retentive vehicle.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

The listing of claims below will replace all previous versions of the claims:

1-89. (canceled)

90. (Previously Amended) A pharmaceutical dosage form for oral administration to a patient providing pulsed gastric release of methylphenidate comprising:

a) a gastric retention vehicle composition comprising about 10 wt-% to about 75 wt-% superdisintegrant, about 2 wt-% to about 12 wt-% tannic acid, and about 20 to about 70 wt-% of a hydrogel, whereby the gastric retention vehicle composition is a homogenous solid matrix and the percentages are calculated with respect to the matrix exclusive of other excipients and the methylphenidate,

b) a plurality of first particles containing methylphenidate that are dispersed in the matrix, wherein the methylphenidate is released from the first particles into the stomach upon contact with gastric fluid, and

c) a plurality of second particles containing methylphenidate that are dispersed in the matrix, wherein each of the second particles is coated with a coating that is impermeable to

methylphenidate and dissolves in gastric fluid, and, after a sufficient amount of the coating is dissolved, the methylphenidate is released from the second particles into the stomach,

wherein, upon contact with gastric fluid the gastric retention vehicle composition expands to a sufficient degree such that the dosage form is retained in the stomach at least until methylphenidate is released from the second particles.

91. (previously presented) A pharmaceutical dosage form of claim 90 further comprising a plurality of third particles containing methylphenidate that are dispersed in the matrix, wherein each of the third particles is coated with a coating that is impermeable to the methylphenidate and dissolves in gastric fluid and the methylphenidate is released from the third particles into the stomach after the methylphenidate is released from the second particles.

92. (Currently Amended) A pharmaceutical dosage form of claim 90 wherein the first particles are coated with a coating that delays release of the methylphenidate from said first[those] particles, with the proviso that the first particles and the second particles are not released at the same time.

93. (Previously Amended) A pharmaceutical dosage form for oral administration to a patient providing pulsed gastric release of methylphenidate comprising:

a) a gastric retention vehicle composition comprising about 20 wt-% to about 70 wt-% of a hydrogel, about 10 wt-% to about 75 wt-% superdisintegrant and about 2 wt-% to about 12 wt-% tannic acid, the percentages calculated exclusive of other excipients or the methylphenidate,

b) a first reservoir containing methylphenidate embedded in said gastric retention vehicle composition wherein methylphenidate is released from the first reservoir into the stomach upon

contact of the dosage form with gastric fluid, and

c) a second reservoir containing methylphenidate embedded in said gastric retention vehicle composition, wherein the second reservoir is coated with a coating that is impermeable to methylphenidate and dissolves in gastric fluid, and, after a sufficient amount of the coating is dissolved, the methylphenidate is released from the second reservoir into the stomach, wherein, upon contact with gastric fluid the gastric retention vehicle composition expands to a sufficient degree such that the dosage form is retained in the stomach at least until methylphenidate is released from the second reservoir.

94. (previously presented) A pharmaceutical dosage form of claim 93 further comprising a third reservoir containing methylphenidate coated with a coating that is impermeable to methylphenidate and dissolves in gastric fluid, wherein the methylphenidate is released from the third reservoir into the stomach after the methylphenidate is released from the second reservoir.

95. (Currently Amended) A pharmaceutical dosage form of claim 93 wherein the first reservoir is coated with a coating that delays release of the methylphenidate from said first[that] reservoir.

96. (original) A pharmaceutical dosage form of claim 93 wherein the gastric retention vehicle composition and the reservoirs are encapsulated.

97-112. (canceled)

113. (previously presented) The pharmaceutical dosage form of claim 90, wherein the methylphenidate is released from the second particles into the stomach about 3 to about 5 hours after administration.

114. (previously presented) The pharmaceutical dosage form of claim 93, wherein the methylphenidate is released from the second reservoir about 3 to about 5 hours after administration.

115. (previously presented) The pharmaceutical dosage form of claim 91, wherein the methylphenidate is released from the third particles into the stomach about 3 to about 5 hours after the methylphenidate is released from the second particles.

116. (previously presented) A method of treating hyperactivity or attention deficit disorder comprising administering a therapeutically effective amount of methylphenidate in the pharmaceutical dosage form of claim 90 to a patient in need thereof.

117. (previously presented) A method of treating hyperactivity or attention deficit disorder comprising administering a therapeutically effective amount of methylphenidate in the pharmaceutical dosage form of claim 93 to a patient in need thereof.

118. (previously presented) The pharmaceutical dosage form of claim 90, wherein the coating comprises a film coating agent selected from the group consisting of water soluble resins, water insoluble resins, waxes, lipids, and enteric resins.

119. (previously presented) The pharmaceutical dosage form of claim 93, wherein the coating comprises polymethacrylate, or a mixture of hydrophilic and hydrophobic film forming agents.

120. (previously presented) The pharmaceutical dosage form of claim 119, wherein the hydrophilic film forming agent is selected from the group consisting of methyl cellulose,

hydroxypropyl methylcellulose, cellulose phthalate, cellulose acetate phthalate, and polyvinyl alcohol.

121. (previously presented) The pharmaceutical dosage form of claim 119, wherein the hydrophobic film forming agent is selected from the group consisting of ethyl cellulose, cellulose acetate, hydroxypropyl methylcellulose phthalate, polyvinyl alcohol maleic anhydride copolymers, β-pinen polymers rosin, partially hydrogenated rosin, and glycerol esters of rosin.

122. (previously presented) The pharmaceutical dosage form of claim 90, wherein the superdisintegrant is selected from the group consisting of cross-linked carboxymethylcellulose sodium, sodium starch glycolate, and cross-linked polyvinyl pyrollidone.

123. (previously presented) The pharmaceutical dosage form of claim 93, wherein the superdisintegrant is selected from the group consisting of cross-linked carboxymethylcellulose sodium, sodium starch glycolate, and cross-linked polyvinyl pyrollidone.

124. (previously presented) The pharmaceutical dosage form of claim 90, wherein the hydrogel is hydroxypropyl methyl cellulose or a mixture of hydroxypropyl methyl cellulose and hydroxypropyl cellulose or a cross-linked acrylate polymer.

125. (previously presented) The pharmaceutical dosage form of claim 93, wherein the hydrogel is hydroxypropyl methyl cellulose or a mixture of hydroxypropyl methyl cellulose and hydroxypropyl cellulose or a cross-linked acrylate polymer.

126. (Canceled)

127. (Canceled)

128. (previously presented) The pharmaceutical dosage form of claim 90, comprising from about 10 wt. % to about 30 wt. % hydroxypropyl methylcellulose, from about 40 wt. % to about 60 wt. % hydroxypropyl cellulose, and about 4 wt. % to about 12 wt. % tannic acid.

129. (previously presented) The pharmaceutical dosage form of claim 90, comprising from about 10 wt. % to about 20 wt. % hydroxypropyl methylcellulose, from about 45 wt. % to about 50 wt. % hydroxypropyl cellulose, and about 4 wt. % to about 6 wt. % tannic acid.

130. (previously presented)The pharmaceutical dosage form of claim 93, comprising from about 10 wt. % to about 30 wt. % hydroxypropyl methylcellulose, from about 40 wt. % to about 60 wt. % hydroxypropyl cellulose, and about 4 wt. % to about 12 wt. % tannic acid.

131. (previously presented) The pharmaceutical dosage form of claim 93, comprising from about 10 wt. % to about 20 wt. % hydroxypropyl methylcellulose, from about 45 wt. % to about 50 wt. % hydroxypropyl cellulose, and about 4 wt. % to about 6 wt. % tannic acid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618